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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,561	10/24/2003	Lone Jeppesen	6598.200-US	9137

23650 7590 11/23/2005

NOVO NORDISK, INC.
PATENT DEPARTMENT
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EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,561

Applicant(s)

JEPPESEN ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 09/26, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 49-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/01/04, 01/08/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
DENMARK 2002 01629 with a filing date 10/28/2002.
2. Claims 1-52 are pending in the application.

Responses to Election/Restriction

3. Applicant's election with traverse without arguments of Group II claims 1-48, in part, in the reply filed on September 26, 2005, is acknowledged. Applicants also elect a species, (E/Z) {4-[3-Biphenyl-4-yl-3-(4-bromo-phenyl)-allylsulfanyl]-phenoxy}-acetic acid, is also acknowledged.

Status of the Claims

4. Claims 1-52 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-48, in part, drawn to compounds/compositions of formula (I), wherein the heteroaryl of variable X_1 represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X_1 is not substituted with heteroaryl, heteroaralkyl, or heteroaralkoxy; the heteroarylene of variable X_2 represents benzofuranylene thereof; the heteroaryl of variable X_3 represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X_3 is not substituted with heteroaryl, heteroaralkyl, heteroaralkoxy.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and

composition from the compounds of the elected invention. The withdrawn compounds/compositions and methods of use contain varying functional groups of the formula (I) having pyridine, piperidine, or oxazole moiety, which differ from those of the elected invention having phenyl or furane moiety, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e., class 546 subclass 249(+) (pyridine), class 546 subclass 184(+) (piperidine), class 548 subclass 215(+) (oxazole), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-48, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-48, in part, not embraced in above elected subject matter, and claims 49-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

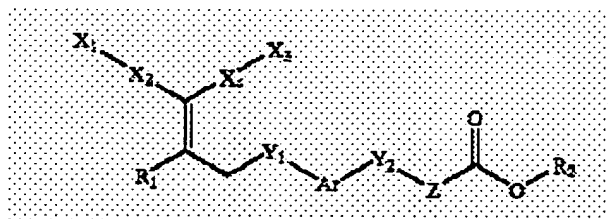
“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

6. Claims 1-48 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jeppesen et al. US 2004/0143006 A1. Jeppesen et al. '006 is 102 (e) reference.

Applicants claim a biphenyl compound/compositions of formula (I) as agents treating diabetes. The instant compounds have been found on pages 9-54 of the specification.

Determination of the scope and content of the prior art (MPEP §2141.01)

Jeppesen et al. '006 disclose a biphenyl compound/compositions of formula (I),



, wherein the variable Ar, X₁, X₂, X₃ and X₄

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independently represents aryl or arylene (i.e., phenyl) optionally substituted with C₁₋₆-alkyl; the variable Y₁ and Y₂ independently represent O or S; the variable Z represents –(CH₂)_n–; the variable R₁ or R₂ independently represents hydrogen or C₁₋₆-alkyl. A number of compounds have been specifically exemplified, see columns 20-26. Jeppesen et al. compounds are agents for treating diabetes.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between instant claims and Jeppesen et al. '006 is that the variable X₃ of instant claims represents aryl optionally substituted with aralkyl, while Jeppesen et al. represents aryl substituted with a variable X₃, and X₃ represents aryl optionally substituted with C₁₋₆-alkyl, at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 1-48 prima facie obvious because one would be motivated to employ the compounds of Jeppesen et al. to obtain instant claimed compound/compositions of formula (I), wherein the heteroaryl of variable X₁ represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X₁ is not substituted with heteroaryl, heteroaralkyl, or heteroaralkoxy; the heteroarylene of variable X₂ represents benzofuranylene thereof; the heteroaryl of variable X₃ represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X₃ is not substituted with heteroaryl, heteroaralkyl, heteroaralkoxy.

The motivation to make the claimed compounds/compositions derives from the expectation that the instant claimed compounds derived from known Jeppesen et al. compounds/compositions would possess similar activities (i.e., agents treating diabetes) to that which is claimed in the reference.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

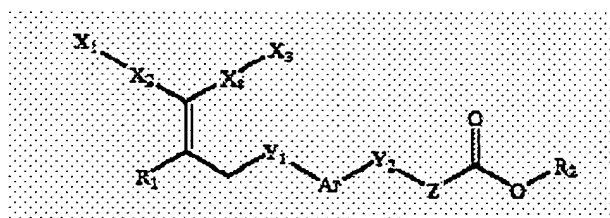
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 45 of Jeppesen et al. co-pending application No. 10/654,699, see US 2004/0143006 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a biphenyl compound/compositions of formula (I) as agents treating diabetes. The instant compounds have been found on pages 9-54 of the specification.

Jeppesen et al. '006 claim a biphenyl compound/compositions of formula (I),



, wherein the variable Ar, X₁, X₂, X₃ and X₄ independently represents aryl or arylene (i.e., phenyl) optionally substituted with C₁₋₆-alkyl; the variable Y₁ and Y₂ independently represent O or S; the variable Z represents – (CH₂)_n–; the variable R₁ or R₂ independently represents hydrogen or C₁₋₆-alkyl. A number of compounds have been specifically exemplified, see columns 20-26. Jeppesen et al. compounds are agents for treating diabetes.

The difference between instant claims and Jeppesen et al. '006 is that the variable X₃ of instant claims represents aryl optionally substituted with aralkyl, while Jeppesen et al. represents aryl substituted with a variable X₃, and X₃ represents aryl optionally substituted with C₁₋₆-alkyl, at the same position.

One having ordinary skill in the art would find the claims 1-48 *prima facie*

obvious because one would be motivated to employ the compounds of Jeppesen et al. to obtain instant claimed compound/compositions of formula (I), wherein the heteroaryl of variable X_1 represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X_1 is not substituted with heteroaryl, heteroaralkyl, or heteroaralkoxy; the heteroarylene of variable X_2 represents benzofuranylene thereof; the heteroaryl of variable X_3 represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X_3 is not substituted with heteroaryl, heteroaralkyl, heteroaralkoxy.

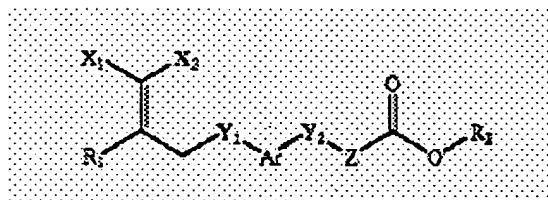
The motivation to make the claimed compounds/compositions derives from the expectation that the instant claimed compounds derived from known Jeppesen et al. compounds/compositions would possess similar activities (i.e., agents treating diabetes) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 39 of Jeppesen et al. co-pending application No. 10/693,161, see US 2005/0070583 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a biphenyl compound/compositions of formula (I) as agents treating diabetes. The instant compounds have been found on pages 9-54 of the specification.

Jeppesen et al. '583 claim a biphenyl compound/compositions of formula (I),



, wherein the variable Ar, X₁, and X₂

independently represents phenyl, aryl or arylene (i.e., phenyl) optionally substituted with aralkyl; the variable Y₁ and Y₂ independently represent O or S; the variable Z represents -(CH₂)_n-; the variable R₁ or R₂ independently represents hydrogen or C₁₋₆-alkyl. A number of compounds have been specifically exemplified, see columns 40-48. Jeppesen et al. compounds are agents for treating diabetes.

The difference between instant claims and Jeppesen et al. '583 is that the variable X₁ of instant claims represents aryl (i.e., phenyl) optionally substituted with C₁₋₆-alkyl, while Jeppesen et al. represents aralkyl, i.e., X₁ represents phenyl substituted with aralkyl, at the same position.

One having ordinary skill in the art would find the claims 1-48 *prima facie* obvious because one would be motivated to employ the compounds of Jeppesen et al. to obtain instant claimed compound/compositions of formula (I), wherein the heteroaryl of variable X₁ represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X₁ is not substituted with heteroaryl, heteroaralkyl, or heteroaralkoxy; the heteroarylene of variable X₂ represents benzofuranylene thereof; the heteroaryl of variable X₃ represents furyl, thienyl, benzothienyl or benzofuranyl thereof, and X₃ is not substituted with heteroaryl, heteroaralkyl, heteroaralkoxy.

The motivation to make the claimed compounds/compositions derives from the

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expectation that the instant claimed compounds derived from known Jeppesen et al. compounds/compositions would possess similar activities (i.e., agents treating diabetes) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Objection

10. Claims 1-48 are objected to as containing non-elected subject matter, i.e., heteroaryl, heteroaralkyl, heteroarylene, heteroaralkoxy, oxazole, or isooxazole, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

11. Claims 46-47 are objected to as having non-patentability weight of preamble "prevention". Elimination of the term "prevention" would obviate the objection.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

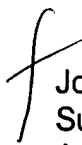
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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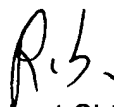
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



TAOFIQ SOLOLA
PRIMARY EXAMINER



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626



Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

November 14, 2005